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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/173,531 10/15/98 ELLISON

R 7409-150-999

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HM12/0321

EXAMINER

PAK, J
ART UNIT

PAPER NUMBER

1616
DATE MAILED:

03/21/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/173,531

Applicant(s)
ELLISON et al.

Examiner
John Pak

Group Art Unit
1616

- ☐ Responsive to communication(s) filed on _____.
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-20 is/are pending in the application.
- Of the above, claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-20 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claims _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☒ Notice of References Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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Claims 1-20 are pending in this application.

Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(1) All treatment method claims must recite administering the arsenic compounds to a patient/human/mammal in need of treatment for [particular disorder].

(2) In claim 2, the term “such” is problematic. First, the use of “such” is confusing in that it can be exemplary or limiting. Second, the reference to “such therapy” is not precise in antecedent basis since the term “therapy” was not used before.

(3) In claim 9, the correct Markush language must have the structure, “selected from the group consisting of ... **and**”

(4) In claim 13, “therapeutic” should be amended to read --- therapeutic agent --- .
Similar situation in claim 14.

(5) In the context of this invention, “other immunomodulators” in claim 16 is unclear and indefinite.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 19-20 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Chen et al. (Blood, Vol 88(3), 8/96, pp. 1052-61).

Chen et al. disclose Ai-Lin 1, a 0.1% arsenic trioxide solution, and another arsenic trioxide solution for IV administration (see Materials and Methods in the paragraph bridging pages 1052 and 1053). Instant claims 19-20 directly read on said arsenic trioxide solutions. The claims are thereby anticipated or at the very least rendered obvious within the meaning of 35 USC 103(a) since a sealed sterile container for IV solution goes without saying in this medical field.

Claims 19-20 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Shen et al. (Blood, Vol 89(9), 5/97, pp. 3354-3360).

Shen et al. disclose Ai-Lin 1, a 0.1% arsenic trioxide solution for IV administration (see Patients and Methods in the paragraph bridging pages 3354). Instant claims 19-20 directly read on said arsenic trioxide solution. The claims are thereby anticipated or at the very least rendered obvious within the meaning of 35 USC 103(a) since a sealed sterile container for IV solution goes without saying in this medical field.

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Claims 19-20 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Zhang et al. (translation of Chinese J. of Hematology, Vol. 17, 2/96).

Zhang et al. disclose an arsenic trioxide solution for IV administration (see Method of Therapy, third page of the translation). Instant claims 19-20 directly read on said arsenic trioxide solution. The claims are thereby anticipated or at the very least rendered obvious within the meaning of 35 USC 103(a) since a sealed sterile container for IV solution goes without saying in this medical field.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of Shimotsuura et al., Shen et al., Chen et al., Zhu et al., Sun et al. and Zhang et al.

Shimotsuura et al. (English translation provided) disclose the antineoplastic actions of arsenic trioxide. See the entire article, in particular the Conclusion section in p. 49 of the original article. See also pages 52-53 for an English summary, as well as the provided English translation.

Shen et al. disclose the use of arsenic trioxide in the treatment of APL (see the entire article). **Chen et al.** disclose the cellular and molecular mechanisms of arsenic trioxide in the treatment of APL (see the entire article). **Zhu et al.** also disclose the mechanisms of arsenic trioxide in the treatment of APL (see the entire article). **Sun et al.** disclose the use of arsenic trioxide in combination with a Chinese medicines to treat Acute Early Granulocytic Leukemia (see

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the entire article; English translation provided). **Zhang** et al. disclose the use of arsenic trioxide to treat APL (see the entire article; English translation provided).

While the references do not expressly disclose the treatment of practically all cancer types, as claimed, one having ordinary skill in the art would have been motivated to utilize arsenic compounds such as arsenic trioxide to treat solid tumors and other neoplastic diseases as claimed herein because arsenic compounds have been taught to possess antineoplastic properties, in addition to having been clinically demonstrated as being effective in treating leukemia. With regard to the combined therapies with other therapeutics, the motivation to do so arises from the well known expectation in this field that the use of several active antineoplastic agents has the benefit of treating the neoplastic disease by the different actions of several agents with different mechanisms. Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been fairly suggested by the combined teachings of the references.

For these reasons all claims must be refused.

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machines are (703) 308-4556 or (703) 305-3592.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Examiner Pak whose telephone number is (703) 308-4538. The Examiner can normally be reached on Monday through Thursday from 8:00 AM to 5:30 PM. The Examiner can also be reached on alternate Fridays. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. José Dees, can be reached on (703) 308-4628. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.



JOHN PAK
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GROUP 1600